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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,746	03/05/2002	Ute Griesbach	C'U-2652 RIS	8970

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07/16/2004

Richard J Streit
Ladas & Parry
Suite 1200
224 South Michigan Avenue
Chicago, IL 60604

EXAMINER

MAIER, LEIGH C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/936,746	Applicant(s) GRIESBACH ET AL.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 3, 2004 has been entered.

Any objection or rejection not specifically repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 11, 17 and 23 are currently amended. Claims 11-28 are pending.

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The independent claims 11, 17, and 23 have been amended to include the limitation "wherein the side chains comprise β -(1,3) linkages or 0-4 consecutive β -(1,6) linkages." (emphasis added)

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Applicant cites page 2 for support for the italicized portion of the added limitation, but the examiner is unable to find said support at page 2 or anywhere else in the specification, as originally filed.

Claim Rejections - 35 USC § 112

Claims 11-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims 11, 17, and 23 have been amended to include the limitation “with *naturally intact* β -(1,3) side chains . . .” (emphasis added) It is not clear whether or not the phrase “naturally intact” actually limits the side chains. That is, would “with naturally intact β -(1,3) side chains” have a different meaning than “with β -(1,3) side chains”?

Claim Rejections - 35 USC § 103

Claims 11-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZULLI et al (US 6,342,486) in view of WEITKEMPER et al (6,444,659) and JP 5-279239. Because the reference is in Japanese, the examiner is relying on the Derwent abstract to indicate its contents.

ZULLI teaches as set forth in previous Office actions. The reference further teaches that the cosmetic compositions comprising the disclosed glucan have utility for the treatment of aging and/or rough skin. See abstract; col 2, lines 53-55; and col 8, lines 30-67. The reference does not disclose the addition of chitosan.

WEITKEMPER teaches as set forth in previous Office actions.

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JP 5-279239 teaches that succinyl- and carboxymethyl-chitosan are particularly good humectants with utility for preparing cosmetic compositions.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a cosmetic composition comprising the glucan disclosed by ZULLI and administer said composition for the treatment of aging and/or rough skin because of the art-disclosed utility. One of ordinary skill would be motivated to modify said composition by the addition of derivatized chitosans, known to have utility for the preparation of cosmetic compositions. The artisan would reasonably expect success in preparing and using said compositions because of the moisture-retaining properties of these chitosan derivatives.

Applicant states that the “presently claimed β -(1,3) glucans are not carboxymethylated.” The examiner is not persuaded that the claim would preclude such derivatives. As discussed in the previous Office action, claim 11 recites “chitosans” and then specifically recites derivatized chitosans in the dependent claims. Again, a fair reading of the claims would not preclude derivatized glucans.

With regard to the data purporting to show a synergistic effect of the combined components, there are other concerns besides the difficulty in comparing subjects. For example, the measurements, particularly those measuring “roughness” appear very subjective. It is not clear how the aging measurement is calculated. There is no indication whether or not these tests are double-blind, which would appear to be critical for such subjective measurements. There is no disclosed margin of error. It is not clear how large the testing groups are—are there 15 subjects in each group, or are the 15 subjects split into the five groups? Finally, matching

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subjects would not appear to be such an onerous task. Testing could comprise application of different compositions to the same subject.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of U.S. Patent No. 6,497,865 and over claim 6 of U.S. Patent No. 6,497,863. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant compositions and the ones of '865 and '863 all comprise water-soluble β -(1,3) glucans and chitosans. The β -(1,3) glucans are described a bit differently in each case, but they appear to be claiming essentially the same products. This is supported by the fact that the β -(1,3) glucans are prepared in the same manner. See '865 at the paragraph bridging col 1-2; '863 at col 2, lines 22-45; and the paragraph bridging pages 2 and 3 of the instant specification.

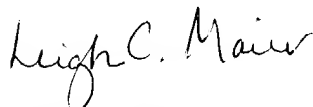
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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
July 12, 2004